

REMARKS

Applicant respectfully requests reconsideration. Claims 1-8, 12-19, 21-23, 45 and 68 were previously pending in this application. By this amendment, Applicant is amending claims 1, 7, 8, 23, 45, and 68 to indicate that the methods relate to prophylactic treatment of a subject not exhibiting symptoms of a streptococcal or staphylococcal infection. Support for the amendment of the claims to include language relating to "prophylaxis" can be found at least at page 12, line 31 through page 13, line 11; page 21, lines 24-30; and page 23, lines 12-15. Support for the amendment of the claims to include language relating to treatment of subjects not exhibiting symptoms of a streptococcal and/or staphylococcal infection can be found at least at page 12, lines 21-29 of the specification as filed. As a result, claims 1-8, 12, 19, 21, 23, 45, and 68 are pending for examination with claims 1, 23, 45, and 68 being independent claims. No new matter has been added.

Rejections under 35 U.S.C. §112, second paragraph

The Examiner rejected claim(s) 1-8, 12-19, 21-23, 45, and 68 under 35 U.S.C. §112, second paragraph as unclear.

The Examiner states that the use of the phrase "reduce the likelihood of infection" is not clear. Although Applicants maintain that the phrase, when read in the context of the specification as filed, indicates that the chance that a subject will incur a streptococcal or staphylococcal infection can be lessened by administration of hyaluronic acid in the methods of the invention, in the interest of expediting the allowance of the claims, Applicants have amended claims 1, 7, 8, 23, 45, and 68 to clarify the meaning of the claim language. Claims 1, 7, 8, 23, 45, and 68 have been amended to indicate that the claimed methods are prophylactic methods of treating a subject for streptococcal and/or staphylococcal infections and to indicate that the subject is not exhibiting symptoms of a streptococcal or staphylococcal infection.

The amendments to claims 1, 7, 8, 23, 45, and 68 clarify that the treatment of the subject is a prophylactic treatment and that the administered hyaluronic acid interferes with streptococcal or staphylococcal binding and/or colonization in the subject.

As set forth in the claims, the administered hyaluronic acid interferes with the adhesion of streptococcal or staphylococcal bacteria and/or displaces streptococcal or staphylococcal bacteria bound to CD44 protein in the subject. As described in the specification as filed, a series

of events may be involved with infection with streptococcal or staphylococcal bacteria. These steps may include: 1) exposure to streptococcal or staphylococcal bacteria; 2) binding of the bacteria to CD44 protein in the subject; 3) colonization of the membrane in the subject; 4) manifestation of a symptomatic infection, which may include inflammation. The claimed methods address the interference and/or displacement of bacteria from CD44 protein and the inhibition of colonization in a subject, both of which are events that can be distinguished from inflammation in the subject. The claims as amended are drawn to methods of prophylactically treating a subject not exhibiting symptoms of a streptococcal (or staphylococcal) infection with hyaluronic acid such that the binding of streptococcal or staphylococcal bacteria to CD44 in the subject is reduced and colonization of the pharynx by streptococcal or staphylococcal bacteria is inhibited. As indicated on page 12, lines 2-10, the inhibition of bacterial binding and colonization of the pharynx in a subject interferes with and reduces the likelihood of the onset of a symptomatic streptococcal or staphylococcal infection in the subject.

Applicants submit that the amendments to the claims clarify the meaning of the claims, thereby obviating the basis for the rejection of claims 1-8, 12-19, 21-23, 45, and 68, under 35 U.S.C. §112, second paragraph.

Accordingly, withdrawal of the rejection of claim(s) 1-8, 12-19, 21-23, 45, and 68 under 35 U.S.C. §112, second paragraph is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 1-8, 12-19, 21-23, 45, and 68 under 35 U.S.C. §103(a) as being unpatentable over Yutaka (JP 6 107 550, published April 19, 1994). Applicants respectfully traverse the rejection.

There are three requirements that must be met to establish a *prima facie* case of obviousness. The Examiner must demonstrate that the reference teaches each and every element of the claimed invention, motivation to modify the teaching in the reference to make the claimed invention, and a reasonable likelihood of success in making the modification. Applicants submit that these three requirements for a *prima facie* case of obviousness have not been met.

The Examiner states at pages 4 and 5 of the Office Action mailed February 8, 2005, that Yutaka teaches “a method of treating a subject to reduce the likelihood of streptococcal or staphylococcal infections”. Applicants submit that the Yutaka reference describes the use of

hyaluronic acid to “cure” inflammation and heal wounds, but does not teach or suggest the use of hyaluronic acid as is instantly claimed. The Yutaka reference suggests the use of hyaluronic acid in a subject to heal inflammation. The Yutaka reference does not disclose or suggest the use of hyaluronic acid to interfere with the adhesion or colonization of streptococcal or staphylococcal bacteria in a subject not exhibiting symptoms of a streptococcal (or staphylococcal) infection or to administer hyaluronic acid prophylactically. As discussed above, Applicants submit that “curing” existing inflammation is not the same as inhibiting adhesion and bacterial colonization, which provides the basis for the instant claims. Applicants respectfully submit that the instantly claimed methods of prophylactically administering hyaluronic acid to a subject not exhibiting symptoms of infection to reduce adhesion of bacteria and/or to displace bacteria bound to CD44 are not suggested or taught by the Yutaka reference and no motivation is provided that would lead one to modify the Yutaka disclosure to make the claimed invention.

As is well established in the law, an effective obviousness rejection must be based on a reference that teaches each and every element of the claimed invention and provide a specific motivation for a skilled artisan to modify the reference in such a way as to obtain the claimed invention. The rejection issued by the Examiner has not demonstrated a specific motivation for the person of skill to modify the elements of the Yutaka reference to obtain the claimed invention and the Yutaka reference does not teach each and every element of the claimed invention. Thus, Applicants respectfully submit that the Examiner has not set forth a *prima facie* case of obviousness in the rejection of claims 1-8, 12-19, 21-23, 45, and 68 under 35 U.S.C. §103(a).

Accordingly, withdrawal of the rejection of claims 1-8, 12-19, 21-23, 45, and 68 under 35 U.S.C. §103(a). is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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